

**ATTACHMENT 2**  
**Questions Proposed for Elimination**

<b>Questions not required by FDA or AABB</b>	
<b>Question</b>	<b>Rationale for eliminating</b>
3. Have you for any reason been deferred or refused as a blood donor or told not to donate?	Nonspecific - picks up many previous minor and/or temporary deferrals. Unpublished focus group data and 2000 AABB Survey of Blood Centers suggest this question is particularly irritating to donors due repetitious reiteration of previous deferrals at every subsequent donation.
28. Are you giving blood because you want to be tested for HIV or the AIDS virus?	1. Not on ARC questionnaire - almost 50% of US donors currently not asked this question. 2. 1999 data from 3 US blood centers, representing 210,000 donors, show that only 0.01%-0.03% answered "yes." 3. Information posted at blood centers, per FDA. 4. Many centers include this in donor educational materials. 5. Message will be reinforced in enhanced educational materials, currently under development.

<b>Questions not recommended/required by FDA but by AABB Standards</b>	
<b>Question</b>	<b>Rationale for Eliminating</b>
12. In the past 12 months have you been given rabies shots?	1. CDC rabies experts find "no compelling medical, epidemiological, or public health justification for this question. Specifically, 1) rabies is not spread by the blood borne route; rather, after entering through a break in the skin or across a mucosal surface the virus replicates in muscle cells and spreads by way of peripheral nerves to the central nervous system; 2) the reported incubation period varies from a few days to more than six years, although 75% of persons become ill in the first 90 days following exposure; and 3) post-exposure treatment would not require injection of any live virus material." Charles Rupprecht, VMD, PhD, Chief, Rabies Section, CDC. 1/31/01 correspondence with Task Force chair. 2. AABB BBTS Standards Program Units concurs with recommendation to eliminate.
13. In the past 6 weeks have you been pregnant, or are you pregnant now? <b>NOTE:</b> It is proposed that "In the past 6 weeks have you been pregnant.." be eliminated, but female donors will be asked if they are pregnant.	1. Based on consultation with the OB-GYN liaison to the Blood Bank/Transfusion Services Program Unit of the Standards Committee (BBTSPU), there is no medical indication to inquire about recent pregnancy. Anemia would be detected by predonation hemoglobin screening, and prospective donors with infected Caesarian sections and episiotomy sites would be symptomatic. 2. AABB BBTS Standards Program Unit concurs with recommendation to eliminate.
17. In the past 12 months have you taken (snorted) cocaine through your nose?	Dropped from AABB BBTSPU Standards, 20th Ed. due to lack of supporting evidence. REDS data do not show intranasal cocaine use to be an independent risk factor for HCV infection.

20A. In the past 12 months have you had a positive test for syphilis?	<ol style="list-style-type: none"> <li>1. Donors will be asked about treatment for gonorrhea or syphilis in the past 12 months.</li> <li>2. Dropping the inquiry about a positive test for syphilis is consistent with approach to hepatitis question, in which the focus is on an actual clinical diagnosis vs. test results.</li> <li>3. The 12/12/91 FDA Memorandum ("...Recommendations for Donor Deferral ...Based on the Results of Syphilis Testing")applies to blood center screening tests; if screening test results are confirmed, donor is deferred. Our interpretation is that deferral is based on test results obtained at a blood center, and does not include testing done at non-blood center facilities. The memorandum does not require or recommend that a question be asked.</li> <li>4. Syphilis testing continues to be a standard blood donor assay. If a donor has been exposed to syphilis, the sensitivity of current tests is such that treated or current infections would be detected.</li> <li>5. Given that highly sensitive syphilis assays are in use, asking if a donor has had a positive test for syphilis is a non-specific and insensitive approach for identifying donors at risk for previous or current syphilis infections.</li> <li>6. Individuals are more likely to know whether they have had syphilis vs. just a reactive test result.</li> </ol>
---	--

### AABB-initiated question in response to FDA document, but a question is not required by the FDA

1. Have you ever donated or attempted to donate using a different name (or another name) here or anywhere else?	<ol style="list-style-type: none"> <li>1. The FDA document upon which this question is based is 21 CFR 606.160(e) April 1999 and states that a "record shall be available from which unsuitable donors may be identified so those products from such individuals will not be distributed." The ability to link or access donor records is a local issue dependent upon the technological capabilities and donor identification systems of each center. It is up to each center to determine how compliance with this regulation will take place, but a specific question such as the one currently in existence is only one possible approach.</li> <li>2. The AABB BBTS Standards Program Unit concurs with the recommendation to eliminate.</li> </ol>
29. Do you understand that if you have the AIDS virus you can give it to someone else even though you may feel well and have a negative AIDS test?	<ol style="list-style-type: none"> <li>1. This question was based on the 4/23/92 FDA Memorandum that states "donors should be informed that there is an interval during early infection when the HIV antibody test may be negative although the infection may still be transmitted." The information which this complex, long question seeks to impart will be reinforced in the enhanced donor educational materials.</li> <li>2. The AABB BBTS Standards Program Unit concurs with the recommendation to eliminate.</li> </ol>
32. Have you read and understood all the donor information presented to you, and have your questions all been answered?	<ol style="list-style-type: none"> <li>1. This AABB-generated question was based on the 4/23/92 FDA Memorandum stating that "information should be written in language that assures that the donor understands the definition of high risk behavior and the importance of self-exclusion. Donors should not be considered suitable unless information about risks can be communicated in the language appropriate to each donor and is constructed to be culturally sensitive to promote comprehension." <b>A fundamental goal of the donor questionnaire revision process is to comply with this guidance, and would eliminate any need to ask this question.</b> Furthermore, most donor questionnaires submitted in response to the 2000 AABB Survey of Blood Centers, contain the elements of this question in the donor consent portion of questionnaires. It is recommended that all blood centers include the elements of this question in the donor consent language. Blood centers would have the option of orally soliciting this information at the conclusion of the screening process.</li> <li>2. The AABB BBTS Standards Program Unit concurs with the recommendation to eliminate.</li> </ol>